

REMARKS/ARGUMENTS

Claims 1, 7, 8, 14-23, 29, 30, 42, 44-46, 48, 49, 54, 63, 64 and 66 are pending in the application. Claims 1, 7, 42 and 54 are rejected. Claims 8, 14-23, 29, 30, 44-46, 48 and 49 are objected to. Claims 63, 64 and 66 are withdrawn from consideration. Claims 2-6, 9-13, 24-28, 31-41, 43, 47, 50-53, 55-62 and 65 have been canceled.

Claims 1 and 42 have been amended and claims 63, 64 and 66 have been canceled without prejudice. Applicants reserve the right to file a divisional application on the non-elected subject matter.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The examiner has pointed out that claim 1 is drawn to a "composition" comprising a compound of formula I and concludes that the language is confusing since the remaining claims 7-8, 14-23, 29-30, 42, 44-46, 48, 49 and 54 are drawn to compounds. By the present amendment claim 1 has been amended by deleting the words "a composition comprising a". Claim 1 has been converted to a compound claim as recommended by the examiner.

Claims 1 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The examiner has stated that the substituents listed on page 3 of the amendment filed on July 3, 2006 for amended claims 1 and 7, *i.e.* "wherein R¹ and R² are optionally and independently substituted.....", are not found in the specification and that the set of substituents in question were described on page 19 of the specification as being substituents on the Q moiety. The language in question appears on page 6 of the specification at lines 3-13 and, therefore, is not new matter as suggested by the examiner. The examiner has also indicated that the NR¹R² ring structure substituents only find antecedent basis on page 17, paragraph (g). Applicants submit that the language referred to on page 6 of the

specification refers to R^1 and R^2 whether they are independent or part of a ring.

The language on page 5 of the specification that just precedes the language in question reads as follows:

or R^1 and R^2 taken together with the nitrogen to which they are attached form a saturated 3-13 membered N-linked heteroaryl, wherein, in addition to the N-linking nitrogen, the 3-13 membered heterocyclyl may optionally contain 1-3 additional heteroatoms independently selected from O, S and NH.

The language in question immediately follows the above paragraph on page 6 of the specification. It is clear, therefore, that the reference to R^1 and R^2 refers to the preceding paragraph. The language on page 17 referred to by the examiner is part of the description in the specification relating to preferred compounds. See page 16 starting at line 20. Applicants have not deleted the disputed language from claim 1 since it was clearly present in the application when filed and, therefore, is not new matter.

Claims 1, 42 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description as well as with the enablement requirement. The examiner has concluded that the description for the claimed scope of the compounds of formula I as a "salt, ester, solvate or amide" is insufficient and ambiguous. Applicants have amended claims 1 and 42 by deleting the words "ester, tautomer, solvate or amide". The words "acid addition, alkali metal and alkaline earth metal" have been added before the word "salt". Support for the pharmaceutically acceptable salts as amended is found on page 46 of the specification wherein specific acid addition, alkali metal and alkaline earth metal salts of the claimed compounds are described.

The examiner has indicated that the claims included $p+q = 4$ compounds in combination with L, R^a , R^5 , R^3 , and R^4 and concluded that absent any description of the seven membered ring compounds, the mere language $p+q = 4$ offers no enablement to one for making and for using such

compounds or their composition. Applicants wish to point out that there are examples in the specification of compounds having 5 membered rings (Ex.61, 62) and 6 membered rings (Ex. 15 and 16). One skilled in the art would be able to prepare compounds of varying ring sizes, including seven membered ring compounds, given the various teachings of the Examples in the specification.

For example, the seven membered ring compounds can be prepared according to the procedures described in the Examples using readily available starting materials. Precursors which can be employed to prepare the seven membered ring compounds include 3-formyl-azepane-1-carboxylic acid benzyl ester (see US 6,645,980 B1); 3-amino-azepane-1-carboxylic acid tert-butyl ester (see WO 2005/16909); and 4-amino-1-benzyl-azacycloheptane (WO 97/32880). All of said starting materials are readily available to those skilled in the art.

Applicants take note of the fact that the examiner has denied the request for rejoinder of claims 63, 64 and 66. The examiner has indicated that claims 63, 64 and 66 lack written description and fail to comply with the enablement requirement. By the present amendment applicants have canceled claims 63, 64 and 66 without prejudice. Applicants reserve the right to file divisional applications on any and all canceled and non-elected material.

Reconsideration of the rejections under 35 U.S.C. 112, first and second paragraphs, is courteously requested.

Claims 8, 14-23, 29, 30, 44-46, 48 and 49 are objected to as being dependent upon a rejected base claim. In view of the amendments made to claim 1 it is believed that the rejection of base claim 1 has been overcome.

In view of the above discussion and the amendments herein made to the claims it is believed that all of the outstanding objections and rejections have been removed.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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